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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,780	09/15/2003	Philippe Bouchard	098501-0305998	7252

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,780

Applicant(s)

BOUCHARD ET AL.

Examiner

Cybillie Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24 and 26-42 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/23/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Detailed Action

The following is responsive to the preliminary amendment received Jan. 23, 2004.

Claims 1-21 are cancelled. New claims 22-42 are added. Claims 22-42 are presented for prosecution on the merits.

Priority

If applicant desires benefit of a previously filed application under 35 U.S.C. 120, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

The Examiner notes that the present application is a continuation of 09/053,152. However, Applicant is respectfully requested to amend the specification to include reference to the parent application and to indicate the status of the parent application as abandoned.

Specification

The specification is objected to because there is no section entitled "Brief Description of the Drawing(s)" as required by MPEP 608.01(f).

Information Disclosure Statement(s)

Applicant's information disclosure statement received Jan. 23, 2004 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Applicant's Remarks

Applicant's remarks received Dec. 19, 2003 have been carefully considered but are moot in view of the following new ground(s) of rejection.

Claim Objection(s)

1. Claims 31 and 36 are objected to because of the following informalities: in claim 31, line 2, "does" should be cancelled and replaced with --dose--.. In claim 36, line 1, -- Human Chorionic Gonadotropin--should be inserted before "HCG" and "HCG" should be deleted and replaced with --(HCG)--.. Appropriate correction is required.

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 22-23, 26-27, 29-32, 35, 37, 38, 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. In claims 22-23 and 35, the limitations "LHRH antagonist", "anti-estrogens" and "LHRH agonist" render the claims vague and indefinite. With respect to the limitation "LHRH antagonist", the specification does not clearly set forth explicitly and with

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reasonable clarity the definition of these limitations. Instead, what is described at page 5, lines 2-7 appears to be merely exemplary (i.e. use of language “such as” and “for example”) and does not describe what would be excluded by the limitations.

Additionally, the limitations “anti-estrogens” and “LHRH agonist” fail to be defined in the specification. Therefore, one of ordinary skill in the art would be unaware of the compounds included and excluded by the limitations.

“The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all of the criteria for patentability and whether the specification meets the criteria of 35 USC 112, first paragraph with respect to the claimed invention.” Please see MPEP 2173.

Because the limitation “LHRH antagonist” is exemplary and does not depict what would be excluded, and descriptions of “LHRH agonist” and “anti-estrogen” are lacking in applicant’s specification, the Examiner respectfully submits that the metes and bounds of the patent protection desired are unclear, and one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed method.

4. Claim 26 recites the limitation “Clomphencitrate” and “Cetrorelix” in line 3. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 27 recites the limitation “Clomphencitrate” and “Cetrorelix” in lines 2 and 3, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejection(s)—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 22, 24, 28-29, 30, 36, 37, 39-40, 41-42 are rejected under 35

U.S.C. 102(a) as being anticipated by Olivennes et al., (reference JR of applicant's 1449).

Olivennes et al. disclose a method of treating women with tubal factor-related infertility with the LHRH antagonist Cetrorelix. Specifically, Olivennes et al. teach subcutaneously administering to the women, 3 mg of cetrorelix on day 8 of the cycle, as well as a second dose 72 hours later. Ovulation was then triggered by administering an effective amount of HCG. Oocytes were retrieved and inseminated. The oocyte transfers were then performed with luteal phase being supported by administration of progesterone beginning four days following HCG administration. Please see page 1383, "Study Protocol". Moreover, LH plasma concentrations were decreased and FSH concentrations before and after cetrorelix administration did not show any noticeable modification. Please see page 1384, "LH Profiles" and "FSH Profiles" The treatment resulted in four clinical pregnancies of which three were ongoing (page 1385, first column, lines 1-6). Finally, Olivennes et al. state that they did not observe an FSH

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decrease following cetorelix administration. Please see page 1385, second column , second full paragraph.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 33-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olivennes et al., supra.

Olivennes et al. do not specifically disclose inducing ovulation with LHRH agonists or native LHRH, especially to reduce the occurrence of ovarian hyperstimulation syndrome. Yet, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the treatment method by administering these agents because Olivennes et al. suggest that administration of these agents along with cetorelix may be advantageous because the occurrence of ovarian hyperstimulation syndrome could be reduced. Please see page 1386, first column, second full paragraph. Such a modification would have been motivated by the reasonable expectation of successfully treating infertile women.

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 22-24, 26-42 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

March 20, 2005


Cybille Delacroix-Muirheid
Patent Examiner Group 1600